REMARKS

I. The Subject Matter of the Claims

In general, the subject matter of the claims relates to antibodies that specifically bind protocadherin pc3.

II. Objection to the Specification

The Examiner objects to the specification indicating that the all amino acid or nucleotide sequences are not appropriately identified by sequence identifiers.

Additionally, Applicant noted several errors in Figure 1A-1C and the sequence listing. It was noted that SEQ ID NO: 98 and the figure containing the amino acid sequence of mouse N-cadherin were inadvertently missing N-cadherin extracellular domain 2. The mouse N-cadherin sequence is a prior art sequence published before the filing date of the application in Miyatani *et al.*, *Science*, 245:631-635 (1989). Applicant has therefore amended SEQ ID NO: 98 and Figure 1 to include the EC2 amino acids. A substitute sequence listing is submitted herewith (Exhibit A), as well as a computer readable copy and a statement under 35 U.S.C. § 1.825 (Exhibit B).

Applicant noted four typographical errors in N-cadherin amino acids presented in Figure 1A-1C. The EC2 amino acid at position 116 in the figure was originally (incorrectly) indicated to be a threonine when the amino acid at the position is a serine, and the EC2 amino acid at position 150 was incorrectly indicated to be a valine instead of a lysine. Similarly, the EC3 amino acid at position 261 was a incorrectly indicated to be a tyrosine instead of a threonine, and the EC5 amino acid at position 481 was a incorrectly indicated to be a phenylalanine instead of a tyrosine. The correct amino acids at the respective positions in the sequence are reflected in the substitute drawings, submitted herewith as Exhibit C.

Applicant submits that none of the corrections of N-cadherin sequences in the figure or the sequence listing include new matter because the N-cadherin sequence was available at the time of filing.

III. Support for the Claims

Support for amendment to claim 18 is found throughout the specification. For example, Example 6, beginning at page 20, line 8, describes methods for purifying and isolating protocadherin-specific polyclonal and monoclonal antibodies.

The amendment includes no new matter.

IV. Patentability Arguments

A. The Rejections of Claims 18, 21-22 Under 35 U.S.C. §101 May Properly Be Withdrawn

The Examiner rejects claims 18 and 21-22 under 35 U.S.C. §101 for assertedly lacking utility as not being different from molecules found in nature. Applicant submits that amendment to claim 18 to recite a "purified and isolated antibody" obviates this rejection.

The Examiner also rejects the claims under 35 U.S.C. §101, asserting that the invention is not supported by a specific and substantial asserted or established utility. MPEP 2107 (II) states that to provide evidence of utility, an applicant should explicitly identify a specific and substantial utility for the claimed invention and provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing. MPEP 2107 also states that a rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.

The claimed invention is *inter alia* directed to an antibody substance that binds to protocadherin pc3 and a hybridoma that secretes a monoclonal antibody specific for pc3. The specification sets out at page 7, lines 1-4 that antibodies of the invention are useful for purifying protocadherin pc3, identifying tissue or cellular expression of protocadherin pc3, and also as antagonists of binding activities of protocadherins, for example, cell-cell interaction. The specification also discloses, at page 2, lines 10-17, that the first cadherins described were identified by their unique immunological characteristics and tissue localization. For example, isolation of uvomorulin, one of the first cadherins identified, was carried out using anti-serum directed against an unknown surface protein (Vestweber *et al.*,

Exp. Cell Res. 152:169-178, 1984, abstract submitted herewith) and later localized to certain tissue sites using rabbit anti-serum (Boller *et al.*, *J. Cel Biol.* 100:327-32, 1985, full text included herewith). These results indicate that even an antibody to an unknown cell surface protein has substantial utility as recognized by one of ordinary skill.

It is well-established in the art that an antibody is useful in purifying a protein from its cellular environment and localizing a protein to a specific tissue or cellular fraction. It was also well-established at the time of filing that protocadherins mediate cell-cell aggregation, and that an antibody to a protocadherin (specifically pc43) is useful in isolating and modulating protocadherin activity. The art is replete with examples of antibodies useful for purifying and isolating proteins of interest for further experimentation (See Vestweber *et al.*, *supra*; Boller *et al.*, *supra*), thereby providing a sound, objective basis for a substantial and credible utility for the antibodies of the invention. Therefore, a person of ordinary skill would readily recognize that an antibody to protocadherin pc3 possesses a specific, substantial and credible utility of purifying protocadherin pc3, localizing the protocadherin to specific tissue sites, and modulating protocadherin pc3 cell adhesion activity.

Thus, the rejection of claims 18 and 21-22 under 35 U.S.C. § 101 may properly be withdrawn.

B. The Rejection of Claims 18, 21-22 Under 35 U.S.C. §112, First Paragraph, May Properly Be Withdrawn

The Examiner rejects claims 18 and 21-22 under 35 USC § 112, first paragraph, asserting that the claimed invention, in reciting "protocadherin pc3," was not described in a manner sufficient to convey that the inventor had possession of the invention. The Examiner alleges that the invention is directed to a genus of protocadherin pc3 molecules including structural variants.

Applicant submits that amendment to claim 18 to recite the sequence identifier SEQ ID NO: 110 for protocadherin pc3 obviates this rejection.

C. The Rejection of Claims 18, 21-22 Under 35 U.S.C. §112, Second Paragraph, May Properly Be Withdrawn

The Examiner rejects claims 18 and 21-22 under 35 USC § 112, second paragraph, for asserted indefiniteness in the recitation of the term "protocadherin pc3." Applicant submits that amendment to claim 18 to include a sequence identifier for protocadherin pc3 obviates this rejection.

V. Conclusion

For the reasons given above, Applicants submit that claims 22-24 are in condition for allowance and request expedited notice of the same.

Respectfully submitted,

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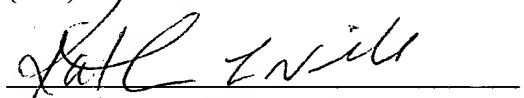
May 7, 2004 By 

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